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EXAMINER	
DORNA, CARRIE R	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,144	NICITA, GIULIO	
	Examiner	Art Unit	
	Carrie Dorna	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-53,55,60 and 62-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *67* is/are allowed.

6)☒ Claim(s) *31-53,55,60 and 62-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to the amendment filed 12 May 2010. The Examiner acknowledges the amendments to claims 31-36, 38, 40-44, 48-53, 55, and 60, and the cancellation of claims 54, 56-59, and 61, as well as the addition of claims 65-67. Claims 31-53, 55, 60, and 62-67 are now pending.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 1 August 2002. It is noted, however, that applicant has not filed a certified copy of the FI2002A000145 application as required by 35 U.S.C. 119(b).

Claim Objections

3. **Claims 48, 62, and 63** are objected to because of the following informalities:

- Claims 48, 62, and 63 each read "surgically implanting.", and should read -- surgically implanting--

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 39, 44-47, 55, 60, and 62-66** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "said membrane of bovine pericardium" in claim 39 renders this claim indefinite as "membrane of bovine pericardium" is not positively required in claim 38.

Claim 44 recites the limitations "the length a-a", "the length b-b", "the length c-c", "the length b-c", "the length d-y", "the total length d-z", "the length e-f", "the distance h-h", "the distance g-g", "the distance i-i", and "the length h-i". There is insufficient antecedent basis for these limitations in the claim.

Claim 46 recites the limitations "the length a-a", "the length b-b", "the length c-c", "the length b-c", "the length d-y", "the total length d-z", "the distance y-x", "the distance x-e", "the length e-f", "the distance h-h", "the distance g-g", "the distance i-l", and "the length h-l". There is insufficient antecedent basis for these limitations in the claim.

Claims 48-53, 60, and 62-66 each recite that the surgical approach is "possibly 'tension free'". The use of the term "possibly" renders the metes and bounds of the claims indefinite as it is unclear what exactly is required by these claims. The meaning of "possibly" equates to "may or may not", which means that the surgical approach of these claims "may or may not" be "tension free".

Claim 55 recites the limitations "the said device" in lines 2, 3, and 5, and "the front arms" in line 5. There is insufficient antecedent basis for this limitation in the claim as this claim depends from cancelled claim 54.

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the positioning of the front

arms of the device is guaranteed by dissections made in the tendineous arch of the levator ani. The method recited by claim 55 merely states that the device is positioned inside the vaginal cavity, dissections are made in the tendineous arch of the levator ani, and the position of the front arms is guaranteed. There is a gap in the relationship between the dissection step and the positioning step of the front arms.

Claim 62 recites the limitation "the flat implantable device" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 63 recites the limitation "the flat implantable device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 64 recites the limitation "the flat implantable device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 65 recites the limitation "the flat implantable device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 66 recites the limitation "the flat implantable device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 62-66 each recite "inserting the said device into the vaginal cavity of the patient by means of surgical approach...selected from the group consisting of vaginal surgery, mixed vaginal/abdominal surgery, vagina/laparoscopical surgery, and mini-invasive surgery, wherein when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises:" (emphasis added). This language renders claims 62-66 indefinite as the broadest reasonable interpretation of these claims is that any one of a variety of surgical approaches may be selected

(vaginal or mixed vaginal/abdominal or vaginal/laparoscopical or mini-invasive). Therefore, the method steps following "said method comprises:" are required only if "vaginal surgery" is the selected surgical approach.

Claims 45, 47, and 60 are rejected as they are dependent on rejected claims 44 and 46.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claims 31-33, 35-37, 40, 41, and 44-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil).

Regarding **claim 31**, Landgrebe et al. teaches a flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs (col. 2, lines 6-11), having a central body (*Figure 1, base,* 1) with a trapezoid shape with small and large bases and four arms (*Figure 1, projections,* 5-8) (col. 2, lines 30-35, 37, 42, 45-46, and 55), comprising: a front portion (*Figure 1,* region of *corner,* 2) corresponding to the smaller base of the trapezium (col. 2, lines 30-35), from the ends of which branch off two front arms (5 and 6) (col. 2, lines 37 and 42); a central portion (*Figure 1,* central portion of *base,* 1) corresponding to the central part of the trapezium; a rear portion (*Figure 1,* portion between *corners,* 3 and 4) corresponding to the larger

base of the trapezium (col. 2, lines 30-35), from the ends of which branch off two rear arms (7 and 8) diverging from each other and parallel to the sides of the trapezium (col. 2, lines 45-46 and 55); characterized in that the said two front arms (5 and 6) branch off from the front portion (region of *corner*, 2) in opposite directions and are coaxial with each other and parallel to said smaller base (These arms are coaxial when the device is folded in half longitudinally. These arms are also considered to be essentially parallel to the side portions of the smaller base of the trapezium; see *Figure 1*). Landgrebe et al. does not teach that the central portion has a hole and a cleft.

However, Rehil teaches a flat implantable device for correcting organ placement comprising a central portion (*Figure 1*, *patch*, 9) that has a central hole (*Figure 1*, hole in *patch*, 1) from which starts a cleft (*Figure 1*, *slit*, 14) (col. 4, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the hole and cleft of Rehil in the device of Landgrebe et al., because a hole and a cleft allow the implant to surround the desired prolapsed organ to provide additional support (Rehil, col. 4, lines 30-34).

Regarding **claim 32**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. and Rehil teach that said cleft (Rehil, 14) longitudinally cuts the rear portion (Landgrebe et al., portion between *corners*, 3 and 4) of said central body (Landgrebe et al., 1) (*see* Rehil, *Figure 1*).

Regarding **claim 33**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. and Rehil teach that said cleft (Rehil, 14) longitudinally

cuts the front portion (Landgrebe et al., region of *corner,* 2) of said central body (Landgrebe et al., 1) (*see* Rehil, *Figure 1*).

Regarding **claim 35**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. and Rehil teach that said cleft (Rehil, 14) transversely cuts the right central portion (Landgrebe et al., central portion of *base,* 1) of said central body (Landgrebe et al., 1) (*see* Rehil, *Figure 1*).

Regarding **claim 36**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. and Rehil teach that said cleft (Rehil, 14) transversely cuts the left central portion (Landgrebe et al., central portion of *base,* 1) of said central body (Landgrebe et al., 1) (*see* Rehil, *Figure 1*).

Regarding **claims 37, 40, and 41**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. teaches that said material with a reticular or laminar structure is a mixture of monofilament polypropylene and polyglactin (col. 3, lines 12-27).

Regarding **claims 44-47**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. teaches that the implant is intended to achieve anatomically adequate and permanent displacement of the bladder neck, and to correct pelvic prolapse in that vicinity (col. 1, lines 11-18). Landgrebe et al. also teaches that the area of the trapezium (1) is about 30-50 cm^2 (col. 2, lines 30-35). Landgrebe et al. and Rehil are silent as to the specific dimensions of each portion of the implant.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the dimensions of

Landgrebe et al. and Rehil to match those specified in claims 44-47 because Applicant has not disclosed that an implant having those particularly claimed dimensions versus dimensions outside of those specified ranges provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an implant of the dimensions described in Landgrebe et al. and Rehil because it will provide adequate and secure support to prolapsed organs to correct anatomical deficiencies (Landgrebe et al., col. 1, lines 11-18; Rehil, col. 4, lines 30-34). Therefore, it would have been an obvious matter of design choice to modify Landgrebe et al. and Rehil to obtain the invention as specified in claim 44-47.

8. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claim 31 above, and further in view of U.S. Patent Application Publication No. 2003/0212460 (Darois et al.).

Regarding **claim 34**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31. Landgrebe et al. and Rehil do not teach that said cleft longitudinally cuts both the front and rear portions.

However, Darois et al. teaches a flat implantable device (*Figure 16, prosthesis,* 20) for repairing anatomical defects or weaknesses, comprising: a central body having a cleft that longitudinally cuts both the front portion (*Figure 16, first segment,* 80A) and the rear portion (*Figure 16, second segment,* 80B) of the central body (see *Figure 16*; [0053]; [0106]). It would have been obvious to one of ordinary skill in the art at the time

of the invention to modify the cleft in the device of Landgrebe et al. and Rehil such that the cleft longitudinally cuts both the front and rear portions of the central body as taught by Darois et al., because a cleft that longitudinally cuts both the front and rear portions of the central body and a cleft that only cuts either the front or rear portion of the central body are substitutable as long as the device securely wraps around the organ to be supported when implanted.

9. **Claims 38 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claim 37 above, and further in view of U.S. Patent No. 6,355,065 (Gabbay).

Regarding **claims 38 and 39**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 37. Landgrebe et al. and Rehil do not teach that the material is bovine pericardium.

However, Gabbay teaches a flat implantable device (*Figure 1, apparatus,* 10) that is composed of bovine pericardium that has been treated with glutaraldehyde and heparin (col. 2, lines 40-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to form the device of Landgrebe et al. and Rehil from bovine pericardium that has been treated with glutaraldehyde and heparin as taught by Gabbay, because bovine pericardium treated in this manner is substitutable for a synthetic material as it encourages tissue ingrowth to further anchor the implant.

10. **Claims 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as

applied to claim 37 above, and further in view of U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.).

Regarding **claims 42 and 43**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 37. Landgrebe et al. and Rehil are silent as to the pore size of the material.

However, Thierfelder et al. teaches a flat implantable device (*Figure 1, article, 10*) that is formed from polyester mesh, and has holes having diameter comprised between 0.01 cm and 0.05 cm (about 1.016 mm to about 1.397 mm, [0097]), necessarily at a distance from each other of between 0.06 cm and 0.1 cm (pore density is between 50 and 400 pores per square inch, [0097]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Landgrebe et al. and Rehil to have the pore size and pore density of Thierfelder et al., because pores of this size and density encourage tissue ingrowth to further secure the implant in the tissue (Thierfelder et al., [0056], [0097]).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide holes having a diameter of 0.03 cm at a distance of 0.08 cm from each other because Applicant has not disclosed that a specific hole diameter of 0.03 cm and a specific distance of 0.08 cm versus another specific hole diameter and specific separation distance provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with holes having a diameter of about 0.01 cm at a density of about 240

holes per square inch because they would encourage and allow tissue to grow into the implant to further secure the implant to the surrounding tissue (Thierfelder et al., [0056]; [0097]). Therefore, it would have been an obvious matter of design choice to modify Landgrebe et al., Rehil, and Thierfelder et al. to obtain the invention as specified in claim 43.

11. **Claims 48-50, 52, 53, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claims 31-33, 35, 36, or 44 above, and further in view of U.S. Patent Application Publication No. 2002/0107430 (Neisz et al.).

Regarding **claims 48-50, 52, 53, and 60**, Landgrebe et al. in view of Rehil teaches all the limitations of claims 31-33, 35, 36, or 44. Landgrebe et al. teaches that the device is implanted to correct female genital prolapse (The vagina is necessarily part of female genitalia as referred to by "decensus genitalis and prolapse", col. 1, lines 11-18). Landgrebe et al. and Rehil do not teach that the device is inserted through the vaginal cavity.

However, Neisz et al. teaches a method for surgically implanting a flat implantable device (*Figure 41, sling,* 42p) in a non-hysterectomized patient suffering a prolapse of the vaginal vault ([0250]), comprising inserting the said device (42p) into the vaginal cavity of the patient by means of a surgical approach that is mixed vaginal/abdominal surgery ([0215]; [0216]; [0250]). It would have been obvious to one of ordinary skill in the art at the time of the invention to implant the device of Landgrebe et al. and Rehil in the manner taught by Neisz et al., because insertion through the vaginal

wall instead of an abdominal incision is less invasive, thus lessens recovery time and pain for the patient.

12. **Claim 51** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) and U.S. Patent Application Publication No. 2003/0212460 (Darois et al.) as applied to claim 34 above, and further in view of U.S. Patent Application Publication No. 2002/0107430 (Neisz et al.).

Regarding **claim 51**, Landgrebe et al. in view of Rehil and Darois et al. teaches all the limitations of claim 34. Landgrebe et al. teaches that the device is implanted to correct female genital prolapse (The vaginal is necessarily part of female genitalia, col. 1, lines 11-18). Landgrebe et al. and Rehil do not teach that the device is inserted through the vaginal cavity.

However, Neisz et al. teaches a method for surgically implanting a flat implantable device (*Figure 41, sling,* 42p) in a non-hysterectomized patient suffering a prolapse of the vaginal vault ([0250]), comprising inserting the said device (42p) into the vaginal cavity of the patient by means of a surgical approach that is mixed vaginal/abdominal surgery ([0215]; [0216]; [0250]). It would have been obvious to one of ordinary skill in the art at the time of the invention to implant the device of Landgrebe et al., Rehil, and Darois et al. in the manner taught by Neisz et al., because insertion through the vaginal wall instead of an abdominal incision is less invasive, thus lessens recovery time and pain for the patient.

Double Patenting

13. Applicant is advised that should claim 64 be found allowable, claim 65 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Additionally, Applicant is advised that should claim 63 be found allowable, claim 66 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 62 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 67. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

14. **Claim 67** is allowed.

15. The following is an examiner's statement of reasons for allowance:

No prior art teach or fairly suggest a method of implanting a device made of material with a reticular or laminar structure for supporting the female pelvic organs, comprising: a central body with a trapezoid shape with small and large bases and four arms; a front portion corresponding to the smaller base of the trapezium, from the ends of which branch off two front arms; a central portion corresponding to the central part of

the trapezium; a rear portion corresponding to the larger base of the trapezium, from the ends of which branch off two rear arms diverging from each other and parallel to the sides of the trapezium; wherein the two front arms branch off from the front portion in opposite directions and are coaxial with each other and parallel to said smaller base; the central portion has a hole and a cleft; and wherein the device is inserted into the vaginal cavity of the patient by means of vaginal surgery that comprises the steps of penetrating the tendineus arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

16. **Claims 62-66** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph and the objections/warning(s) under 37 CFR 1.75, set forth in this Office action.

17. The following is a statement of reasons for the indication of allowable subject matter:

No prior art teach or fairly suggest a method of implanting a device a device made of material with a reticular or laminar structure for supporting the female pelvic

organs, comprising: a central body with a trapezoid shape with small and large bases and four arms; a front portion corresponding to the smaller base of the trapezium, from the ends of which branch off two front arms; a central portion corresponding to the central part of the trapezium; a rear portion corresponding to the larger base of the trapezium, from the ends of which branch off two rear arms diverging from each other and parallel to the sides of the trapezium; wherein the two front arms branch off from the front portion in opposite directions and are coaxial with each other and parallel to said smaller base; the central portion has a hole and a cleft; wherein the device is inserted into the vaginal cavity of the patient by means of vaginal surgery that comprises the steps of penetrating the tendineus arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

Response to Arguments

18. Applicant's arguments filed 13 April 2010 have been fully considered but they are not persuasive.

Applicant contends that Landgrebe does not teach a device comprising two front arms that extend in opposite directions from the smaller base portion and are coaxial with each other and parallel to said smaller base as these arms are "not at all coaxial" and are "generally perpendicular to the smaller base" (arguments filed 13 April 2010, pg. 27). The Examiner does not find this argument to be persuasive as the front arms of

Landgrebe et al. extend from the smaller base portion in opposing directions and are coaxial when the device is folded in half longitudinally. Furthermore, the two arms are essentially parallel to the lateral sides of the smaller base portion. The Examiner's position regarding the broadest reasonable interpretation of at least claim 31 in light of Applicant's relevant arguments has been maintained.

In response to Applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the Examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, both the Landgrebe et al. and Rehil references are directed to implantable devices for correcting anatomical defects wherein a patient's organ(s) has moved into a detrimental position. As such, Rehil provides the motivation for the combination of these two teachings as Rehil teaches that an implant having a hole and a cleft is able to surround the prolapsed organ to more effectively correct its position.

Applicant contends that it would not have been an obvious matter of design choice to modify the dimensions of the device of Landgrebe et al. in view of Rehil to meet the limitations of claims 44-47 as these dimensions are "precise and specific" (arguments filed 13 April 2010, pg. 31), and the cited references in combination do not

result in a device having the shape of Applicant's claimed invention (see remarks addressing Landgrebe et al. and Rehil combination above). The Examiner has maintained the previous rejection of claims 44-47 as Applicant has not disclosed any specific criticality for the claimed dimensions.

Applicant contends that the combination of Landgrebe et al., Rehil, and Neisz would not result in the claimed methods. The Examiner does not find this argument persuasive (see remarks addressing Landgrebe et al. and Rehil combination above).

Regarding the rejection of claims 44-47 under 35 U.S.C. 112, 2nd paragraph for a lack of antecedent basis, the Examiner has maintained the previous rejection. Applicant contends that this rejection is improper as an antecedent basis for these limitations is provided in Applicant's specification. However, the Examiner reminds Applicant that antecedent basis must be provided in the language of the claims. Furthermore, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

19. The Examiner notes Applicant's submission of Appendices A and B regarding a discussion of the anatomical location of the tendineous arch of the levator ani.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Dorna whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D./
Examiner, Art Unit 3735

/John P Lacyk/
Primary Examiner, Art Unit 3735